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this topics and its results express patients' determination in looking for specialized structures having funds for cures, which could lead to important internal and external migration flows. Patients expect from EpaC to raise awareness in the policy makers on the need for approval of the new DAAs and to bring on a campaign of novel therapies equity of access with all Institution independently from the severity of disease stage.

PGI33

ASSESSING GAS-RELATED SYMPTOMS AND THEIR ASSOCIATED IMPACT ON THE DAILY LIFE OF THE GENERAL POPULATION AND IRRITABLE BOWEL SYNDROME PATIENTS: INTERNATIONAL DEVELOPMENT OF A QUESTIONNAIRE–QUALITATIVE STEPS

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OBJECTIVES: To develop a self-report questionnaire to evaluate gas-related symptoms (bloating, flatulence, belching, stomach rumbling and bad breath) and their impact on daily life for Irritable Bowel Syndrome (IBS) patients and healthy subjects complaining of gas-related symptoms. **METHODS:** A literature review and gastroenterologist interviews (n=6) supported development of a preliminary conceptual framework which was discussed with and validated by an international expert committee. Then, semi-structured focus groups and face-to-face interviews with IBS patients (n=28) and healthy subjects (n=27) complaining of gas-related symptoms were conducted in France, Spain and the UK. Qualitative analysis confirmed the questionnaire conceptual framework, which was finalized with the expert committee. Questionnaire items were generated simultaneously in French, Spanish and UK English, with item content based on subjects' quotations. Iterative rounds of cognitive debriefing interviews with IBS patients (n=15) and healthy subjects (n=15) were subsequently conducted to assess questionnaire understanding, acceptability and content validity across countries. **RESULTS:** Eight gas-related symptoms (bloated feeling, distension, flatulence, and odorous flatulence, sensation of difficult gas evacuation, stomach rumbling, belching and bad breath) were identified and described by the subjects in terms of severity and/or duration. Quality of life domains impacted by these symptoms were: emotional, clothing, diet, cognitive function, physical appearance, social life, work life, sleep, sexual life, physical activity, activities of daily living and partner relationships. Both a 24-hour recall symptom diary (18 items) and a 7-day recall impact questionnaire (26 items) were generated supported by the qualitative findings. Comprehension testing to confirm the relevance and understanding of the instruments is on-going. **CONCLUSIONS:** The questionnaires were developed following a rigorous methodology based on comprehensive qualitative research. Both gas-related symptoms and their associated impact are assessed in a manner appropriate for two populations. This makes it a unique tool to be included in clinical programs. The next step is to perform psychometric validation.

PGI34

A PATIENT-REPORTED OUTCOME MODEL FOR CROHN'S DISEASE

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OBJECTIVES: Research into the impact of Crohn's Disease (CD) and its treatment on the patient is reliant on dated generic questionnaires of limited relevance. These measures ask questions of limited relevance to the population and miss crucial aspects of the illness experience. As part of a study to develop CD-specific patient-reported outcome (PRO) measures, qualitative interviews were conducted with CD patients in order to model the impact of the disease on the patient. **METHODS:** Interviews were conducted with CD patients recruited from out-patient clinics. The interviews, which took the form of focused conversations covering all aspects of the impact of CD and its treatment, were audio-recorded. The interview transcripts were analysed to identify the symptoms, activity limitations and QoL impairments resulting from CD. This analysis employed the WHO International Classification of Functioning, Disability and Health (ICF) and the needs-based quality of life (QoL) model. **RESULTS:** Thirty patients (60% female; aged 25-68; mean (SD): 47.9 (14.3) years) were interviewed. Participants had a wide range of CD duration (2-40; mean (SD): 14.3 (13.4) years). Nearly 3,000 statements relating to the impact of CD were identified. These fell into 3 major categories; symptoms (including pain, fatigue and emotional impairment), activity limitations (examples; walking, lifting and jobs around the house) and QoL. Needs affected by CD included autonomy, preoccupation with CD, self-consciousness and reduced socialisation. **CONCLUSIONS:** The findings from the interviews indicate that CD has three major types of impact; symptoms, activity limitations and QoL. All three should be addressed in CD audit, clinical trials and when evaluating clinical practice. Items generated from the interviews will be used to form a new suite of PRO measures specific to CD.

PGI35

HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH HAEMOPHILIA AND INHIBITORS ON PROPHYLAXIS WITH ANTI-INHIBITOR COMPLEX CONCENTRATE: RESULTS FROM THE PRO-FEIBA STUDY

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OBJECTIVES: Patients with hemophilia A and inhibitors are at high risk for severe bleeding and progression of joint disease with consequent deterioration of their health-related quality of life (HRQoL). The Pro-Feiba Study was designed to assess clinical and quality of live outcomes comparing prophylaxis to on demand therapy. **METHODS:** A prospective, randomized, crossover study (Pro-FEIBA Study) aimed to evaluate safety, efficacy and HRQol of AICC for bleeding prophylaxis in hemophilia A patients >2 years with high-responding inhibitors. The study compared 6 months of AICC prophylactically dosed at 85 U/kg ±15% on 3 non-consecutive days per week with 6 months of on-demand therapy (85 U/kg ±15%). The 2 study periods were separated by a 3-month washout (patients used on-demand therapy). Quality of life in patients >14 years was assessed at the beginning and end of each study period with 2 generic instruments: the Short-Form 36 (SF-36) and the EQ-5D. **RESULTS:** Nineteen subjects, of 26 valid patients , were >14 years and potentially evaluable for HR-QoL. Of these, 18 patients (mean age: 32.6 years; min-max: 16.1-62.8) completed SF-36 and/or EQ-5D questionnaires at each time point. Sixteen patients completed both the SF-36 and the EQ-5D at the beginning and end of each study period, 1 patient completed only the SF-36, and 1 patient completed only the EQ-5D. A comparison of the 2 periods showed a trend towards HRQoL improvement favouring prophylaxis. Differences between the 2 study period for SF-36 physical component summary (PCS) were statistically significant in "good responders" (≥50% bleeding episodes reduction) (p=0.018). PCS differences were statistically significant in all evaluable subjects when measured before and after prophylaxis (p=0.047). The EQ-5D health profile showed an improvement trend toward prophylaxis. **CONCLUSIONS:** AICC prophylaxis significantly improved HRQoL as compared with episodic treatment. Larger cohorts and longer follow-up are necessary to confirm these data.

PGI36

RELATIONSHIP BETWEEN CLINICAL SEVERITY AND HEALTH RELATED QUALITY OF LIFE IN CHRONIC LIVER DISEASES

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OBJECTIVES: To assess the relationship between the type of chronic liver diseases (CLDs), clinical severity and patients' HRQoL. **METHODS:** A naturalistic, multicentre study has been conducting to identify and test quality of care indicators. Adult CLDs patients (age>18 years) have been enrolling at gastroenterology unit of 3 Italian hospitals. We are collecting socio-demographic, clinical and HRQoL data with the EQ-5D-3L. Patients are sub-grouped according to CLD type and to clinical severity using the modified Child-Turcotte-Pugh score: with this instrument, patients are classified as non-cirrhotic, early cirrhotic (class A), advanced cirrhotic (classes B and C). We conducted Kruskall-Wallis tests to assess relationship between EQ-5D-VAS score and disease type or severity score. **RESULTS:** Results are based on data from 2,221 patients (67% male, median age=62 years), classified into the following subgroups: HCV or HBV chronic hepatitis (36.0%), compensated cirrhosis (CC, 23.5%), hepatocellular carcinoma (HCC, 19.8%), decompensated cirrhosis (DC, 13.5%), patients in evaluation or listed for liver transplant (LT, 7.2%). Non-cirrhotic patients (HCV or HBV chronic hepatitis) had significantly (p<0.001) higher median VAS (80) than patients with any other CLD types (70). In contrast, patients listed for LT had the lowest (p<0.05) median VAS (65) and the highest proportion of patients (58.1%) in Child class B-C. DC patients had a median VAS not significantly different from that of HCC or CC patients (70 versus 70 and 73, respectively). On the other hand, DC patients in child class A showed a significantly (p<0.05) higher median VAS (72.5) than HCC and CC patients in class B-C, who had a median VAS of 70 and 60, respectively. **CONCLUSIONS:** HRQoL of CLDs patients is significantly related with the Child-Turcotte-Pugh severity score. These results could be useful to understand the impact of the disease severity on patients' HRQoL and guide some decisions in clinical care.

PGI37

FINALISATION AND PSYCHOMETRIC VALIDATION OF A NEW QUESTIONNAIRE MEASURING PATIENT SATISFACTION WITH ANTI-TNF TREATMENTS IN SEVERE CROHN'S DISEASE

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OBJECTIVES: Crohn's disease is a chronic inflammatory bowel disease. Severe Crohn's disease management includes anti-Tumor Necrosis Factor (anti-TNF) drugs differing from treatments used in early stages in terms of efficacy, safety and convenience. To understand how specificities of anti-TNF treatments are perceived by patients, the Satisfaction for Patients in Crohn's disease (SPACE) questionnaire was developed to measure satisfaction with anti-TNF treatment in patients with severe Crohn's disease. The study objectives were to finalise and psychometrically validate the SPACE questionnaire. **METHODS:** An observational, longitudinal, multicentre study was conducted in patients with severe, active Crohn's disease for which anti-TNF therapy was indicated. The 62-item pilot version of the SPACE questionnaire was completed by patients at inclusion, 12 and 13 weeks after first anti-TNF injection. The final structure (i.e. grouping of items into dimensions) was defined using multitrait and regression analyses. Psychometric